

Listing of Claims

1. (Previously Presented) A transdermal drug delivery system comprising a blend of:
 - (a) one or more polymers; and
 - (b) a therapeutically effective amount of one or more drugs, at least one of which is of low molecular weight and liquid at or about room temperatures,
wherein said system is substantially free of water and liquids having a boiling point (i) below processing temperatures and (ii) equal to or greater than the normal boiling points of the at least one low molecular weight drug; and,
wherein one of said one or more polymers is a high shear resistant acrylic-based polymer.
2. (Original) A pressure-sensitive adhesive transdermal drug delivery system suitable for transdermal drug delivery comprising a blend of:
 - (a) one or more solvent-based high shear resistant acrylic-based polymers having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit; and
 - (b) a therapeutically effective amount of one or more drugs, at least one of which is of low molecular weight and liquid at or about room temperatures, wherein the transdermal drug delivery system forms a polymer matrix which has sufficient tack and shear to remain in place under conditions of use.
3. (Original) A pressure-sensitive transdermal drug delivery system as claimed in claim 2, wherein the one or more high shear resistant acrylic-based polymers have a shear resistance which is greater than or equal to 100 hours at 4 pounds per square inch and 72° Fahrenheit.
4. (Original) A pressure-sensitive transdermal drug delivery system as claimed in claim 3, wherein the one or more high shear resistant acrylic-based polymers have a shear resistance which is greater than or equal to 100 hours at 8 pounds per square inch and 72° Fahrenheit.

5. (Original) A pressure-sensitive transdermal drug delivery system as claimed in claim 2, wherein the system is substantially free of water and liquids having a normal boiling point below processing temperatures and also about equal to or greater than the normal boiling points of the one or more low molecular weight drugs.

6. (Previously Presented) A pressure-sensitive transdermal drug delivery system as claimed in claim 2, wherein the one or more drugs are present in a range of 1 to 40 weight per cent, based on the dry weight of the total transdermal system.

7. (Original) A pressure-sensitive transdermal drug delivery system as claimed in claim 2, wherein the one or more high shear resistant acrylic-based polymers have a weight average molecular weight in the range of about 600,000 to about 1,000,000 daltons.

8. (Original) A pressure-sensitive transdermal drug delivery system as claimed in claim 7, wherein the one or more high shear resistant acrylic-based polymers have a weight average molecular weight in the range of about 700,000 to about 900,000 daltons.

9. (Original) A pressure-sensitive transdermal drug delivery system as claimed in claim 8, wherein the one or more high shear resistant acrylic-based polymers have a weight average molecular weight in the range of about 750,000 to about 850,000 daltons.

10. (Original) A pressure-sensitive transdermal drug delivery system for transdermal drug delivery as claimed in claim 2, wherein the one or more drugs comprise nicotine.

11. (Original) A pressure sensitive transdermal drug delivery system as claimed in claim 10, wherein said nicotine is present in its free-base or free-acid form.

12. (Original) A pressure-sensitive transdermal drug delivery system as claimed in claim 2, wherein the one or more acrylic-based polymers comprise a pressure-sensitive adhesive.

13. (Original) A pressure-sensitive transdermal drug delivery system as claimed in claim 12, wherein the one or more high shear resistant, acrylic-based polymers are present in the system in a range of about 10-90 weight per cent, based on the dry weight of the total transdermal system.

14. (Original) A pressure-sensitive transdermal drug delivery system as claimed in claim 2 further comprising a backing material superimposed on one surface of the blend, the backing material being substantially impermeable to the drug contained therein.

15. (Original) A pressure-sensitive transdermal drug delivery system as claimed in claim 14 further comprising a release liner superimposed on a surface of the blend opposite the backing material.

16. (Original) A pressure-sensitive transdermal drug delivery system as claimed in claim 2, wherein the system further comprises an additive selected from one or more of a filler, an enhancer and an excipient.

17. (Original) A method of producing a pressure-sensitive transdermal drug delivery system suitable for a transdermal drug delivery system, comprising the steps of:

(1) producing a blend of:

- (a) one or more solvent-based high shear resistant acrylic-based polymers having a shear resistance of greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit and mixtures thereof; and
- (b) a therapeutically effective amount of one or more drugs, at least one of which is of low molecular weight and liquid at or about room temperatures, wherein the blend is in a solvent system;

(2) forming the blend into a polymer matrix; and

(3) drying the polymer matrix to remove the solvent system to form the transdermal drug delivery system, wherein the system forms a polymer matrix which has sufficient tack and shear for application to a human being.

18. (Original) A method as claimed in claim 17, wherein the high shear resistant polymer comprises a high molecular weight pressure-sensitive acrylic-based polymer.

19. (Previously Presented) A pressure-sensitive adhesive transdermal drug delivery system suitable for transdermal drug delivery comprising a blend of:

- (a) a pressure-sensitive adhesive polymer which consists of one or more solvent-based high shear resistant acrylic-based polymers having a shear resistance which is greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit; and
- (b) a therapeutically effective amount of one or more drugs, at least one of which is of low molecular weight and liquid at or about room temperatures, wherein the transdermal drug delivery system forms a polymer matrix which has sufficient tack and shear to remain in place under conditions of use.

20. (Original) A pressure-sensitive adhesive transdermal drug delivery system as claimed in claim 19, wherein the one or more solvent-based high shear resistant acrylic-based polymers have a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit.

21. (Previously Presented) A method of producing a pressure-sensitive transdermal drug delivery system suitable for a transdermal drug delivery system, comprising the steps of:

- (1) producing a blend of:
 - (a) a pressure-sensitive adhesive polymer which consists of one or more solvent-based high shear resistant acrylic-based polymers having a shear resistance of greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit and mixtures thereof; and

- (b) a therapeutically effective amount of one or more drugs, at least one of which is of low molecular weight and liquid at or about room temperatures, wherein the blend is in a solvent system;
- (2) forming the blend into a polymer matrix; and
- (3) drying the polymer matrix to remove the solvent system to form the transdermal drug delivery system, wherein the system forms a polymer matrix which has sufficient tack and shear for application to a human being.